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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/689,469	10/12/2000	Anne Marie Schmidt	0575/55424-A-PCT-US/JPW/J	7726

7590 07/27/2004

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EXAMINER

YAEN, CHRISTOPHER H

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 07/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/689,469

Applicant(s)

SCHMIDT ET AL.

Examiner

Christopher H Yaen

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 57-60 and 76-78 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 57-60 and 76-78 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Re: Schmidt AM *et al*
Priority Date: 16 April 1999

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/12/2004 has been entered.
2. Claims 57-60 and 76-78 are pending and examined on the merits.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections Maintained - 35 USC § 103

4. The rejection of claims 57-60 and 76-78 under 35 USC 103(a) as being obvious over Hori *et al* (previously cited) in view of Miki *et al* (previously cited) and now further in view of Parkkinen J *et al* (J. Bio. Chem. 1993 September; 268(26):19726-19738) is maintained and newly argued. Applicant argues that the combination of the references do not provide sufficient motivation to arrive at the instant invention, because there is no motivation to use the method taught by Hori *et al* for the screening of agents that inhibit tumor invasion, because Hori *et al* teach a method using neuronal cells. Applicant further asserts that the invention is based on a surprising discovery that the inhibition of

the interaction between amphoterin and RAGE inhibits tumor invasion, and that the rejection based on the combination of Hori *et al* in view of Miki *et al* is based on hindsight.

Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record. At the time of the invention one of ordinary skill in the art would have found it *prima facie* obvious to screen for agents that inhibited the invasiveness of a tumor cells comprising inhibiting the interaction between amphoterin and RAGE, because Hori *et al* already taught a method of screening inhibitors between amphoterin and RAGE in neuronal cells similar to that being claimed. Moreover, it was well established at the time of the invention that tumor cells expressed RAGE, as evidenced by Miki *et al* and that the presence of amphoterin was critical for the invasiveness of cells as demonstrated by Parkkinen *et al*. One of skill in the art would have been motivated to combine the references because it was well established that RAGE was the receptor for amphoterin (see Hori *et al*), and that such receptors were present on the surface of tumor cells (see Miki *et al*). It was also established that the presence of amphoterin at the leading edge of tumor cells (i.e. in the filopodia, membrane ruffles and microspikes – see page 19736 of Parkkinen *et al*) mediated the “pathfinding” functions of the cell which lends to the theory of amphoterin's involvement in cellular invasiveness (see page 19737 and abstract). Therefore, given the fact that tumor cells expressed RAGE and amphoterin and that a method of screening was already available for screening agents that inhibited the interaction between RAGE and amphoterin (as evidenced by Parkkinen *et al*), and given the fact that amphoterin was

Art Unit: 1642

present at the leading edge of advancing or invasive cells and was involved in the "pathfinding" functions, one of skill in the art would have had a reasonable expectation of success in using tumor cells in a method of screening for agents that inhibited invasion by inhibiting the interaction between amphoterin and RAGE.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 571-272-0838. The examiner can normally be reached on Monday-Friday 9-5.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher Yaen
Art Unit 1642
July 20, 2004


GARY NICKOL
PRIMARY EXAMINER